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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/606,779      | 06/28/2000  | John H. Griffin      | SCRIP1180-3         | 1406             |

28213 7590 07/03/2003

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EXAMINER

SAUNDERS, DAVID A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 07/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

X 5

# Office Action Summary

Application No.

60674

Applicant(s)

GRIFFIN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/25/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 2-15 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 2-15 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Claims 2-15 are pending and under examination.

The terminal disclaimer filed on 4/25/03 has overcome the obviousness type double patenting rejection of record.

Claims 2-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Sun et al (of record).

As previously noted in Paper 6, Sun et al show the instant assay that dilutes a sample in Factor V deficient plasma. They teach that their assay may be used to assay for APC resistance with samples from patents on oral anticoagulant therapy (pg 3124, col 1, last full par). They teach instantly recited concentrations of calcium and of APC (pg 3120, col 2, second par). Aspects of dependent claims 2 and 7-15 are also taught therein. Limitations of claims 4-6 are taught at pg 2124, col 1, first full par.

Applicant's arguments filed 4/25/03 have been fully considered but they are not persuasive.

Applicant has merely urged that a patent of the instant family ('757) was issued after consideration of Sun et al and that said patent recites claims encompassing a broader range of calcium and APC concentrations than recited instantly. This argument is unconvincing, since Sun et al was cited during examination of the '757 patent, and applicant has presented none of the arguments, exhibits, or other considerations which led to withdrawal of the reference and allowance of the '757 patent. The examiner set forth a statement of facts in the rejection in Paper 6 of the instant file record, and applicant did not deny these facts; therefore the rejection stands. Examiner's statement of the rejection was based upon the following factual aspects of the reference:

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The APC concentration in ug/ml, shown in Figs 1 and 2 (X-axis), is within the range instantly recited.

The calcium concentration is within the range instantly recited; as may be seen from the following teachings at pg 2120, col 2, second par. the total assay mixture is constituted as follows:

50 uL APTT reagent (line 3).

50 uL Plasma (line 5). This can be 10% normal and 90% Factor V deficient (legend to Figs 1 and 2).

50 uL solution of 30 mmol/L CaCl<sub>2</sub>. (line 6).

50 uL Factor Xa (line 19).

50 uL 25 mmol/L CaCl<sub>2</sub> (line 20).

These additions give a total of 250 uL of assay mixture, with 11 mmol/L of CaCl<sub>2</sub>, which is within the instantly recited range of calcium concentration. Applicant is required to show the examiner has read the reference incorrectly, not to argue that the reference was previously withdrawn.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 382-1644